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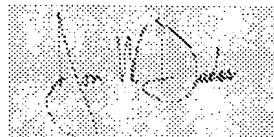
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APPLICATION NUMBER: 60/493,354

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RELATED PCT APPLICATION NUMBER: PCT/US04/25185

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PTO/SB/16 (5-03)

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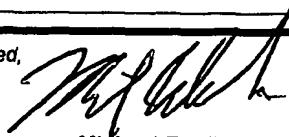
PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

INVENTOR(S)		
Given Name (first and middle [if any])	Family Name or Surname	Residence (City and either State or Foreign Country)
Dr. Martin Dr. Kevin	Lenhardt Ward	Richmond, Va. Richmond, Va.
<input type="checkbox"/> Additional inventors are being named on the _____ separately numbered sheets attached hereto		
TITLE OF THE INVENTION (280 characters max)		
INTRAOCCULAR AND INTRACRANIAL PRESSURE MONITOR		
Direct all correspondence to: CORRESPONDENCE ADDRESS		
<input checked="" type="checkbox"/> Customer Number	30743	<input type="checkbox"/> Place Customer Number Bar Code Label here
OR	Type Customer Number here	
<input checked="" type="checkbox"/> Firm or Individual Name	Whitham, Curtis & Christofferson P.C.	
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ENCLOSED APPLICATION PARTS (check all that apply)		
<input checked="" type="checkbox"/> Specification	Number of Pages	2
<input checked="" type="checkbox"/> Drawing(s)	Number of Sheets	12
<input type="checkbox"/> Application Data Sheet. See 37 CFR 1.76	<input type="checkbox"/> CD(s), Number _____ <input type="checkbox"/> Other (specify) _____	
METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT (check one)		
<input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27.	FILING FEE AMOUNT (\$)	
<input checked="" type="checkbox"/> A check or money order is enclosed to cover the filing fees		
<input checked="" type="checkbox"/> The Director is hereby authorized to charge filing fees or credit any overpayment to Deposit Account Number	50-2041	\$80.00
<input type="checkbox"/> Payment by credit card. Form PTO-2038 is attached.		
The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.		
<input checked="" type="checkbox"/> No.		
<input type="checkbox"/> Yes, the name of the U.S. Government agency and the Government contract number are: _____		

Respectfully submitted,

SIGNATURE



TYPED or PRINTED NAME Michael E. Whitham

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Date 8-8-03

REGISTRATION NO.
(if appropriate) 32,635

Docket Number: 02940323PR

USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

This collection of information is required by 37 CFR 1.51. The information is used by the public to file (and by the PTO to process) a provisional application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 8 hours to complete, including gathering, preparing, and submitting the complete provisional application to the PTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop Provisional Application, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

INTRAOCULAR AND INTRACRANIAL PRESSURE MONITOR

Pressure increase in the brain, contained in the skull, is a serious medical condition that can be life threatening. Intracranial pressure changes can be detected non invasively using acoustic stimulation and analysis. The brain and the skull are coupled resonant systems that will respond in a predictable fashion to pressure increases given the bioboundary conditions. Changes in acoustic damping are correlated with changes in cerebral spinal fluid (CSF) or intracranial pressure (ICP).

There are two "windows" to the interior brain pressure, the ear and the eye. Ear monitoring of changes in CSF pressure have been attempted (Marchbands, 1999), but have not resulted in a feasible clinical device. Direct measures of the skull vibration or using ultrasonic probes have also been attempted with some success. The later is technically complicated, and is not a promising clinical alternative. Eye pressure does correlate with CSF and various approaches have been used since eye pressure assessment is a common ophthalmological procedure. Two types of intraocular pressure measurement have been reported which have various correlations with ICP. These include noncontact air tonometry which measures intraocular pressure (Sheeran 2000, Salman 1997). This technique has produced conflicting results and at best could likely only provide a rough estimate of ICP. The other technique reported is ophthalmodynamometry which is an applanation technique (Draeger 1999, Draeger 2000). This technique applies pressure to the cornea and measures the intraocular arterial pulse wave. Pressure is applied to the corneal surface until the intraocular arterial pulse wave (produced by the ophthalmic artery) is

obliterated. The pressure at which this happens has been termed intracranial arterial pressure and some have used this pressure to infer changes in ICP. However, this measure cannot be equated with ICP.

The present invention capitalizes on the acoustic resonant properties of the eye, a globe that can be modeled accurately as a sphere. Sixty percent of the globe is bounded by bone, representing a high impedance interface. Calculations of resonant frequencies range from approximately 95 -140 kHz. Ultrasonic resonance is expected given the small radius of the eye (~0.75 mm). While not wanting to be limited by initial calculations and relatively few direct measurements, we intend to sweep tones from well below and well above projected resonant frequency. Various anatomical features and less than sphere geometry make exact predictions difficult. Nonetheless a wide range of frequency sweeping to ensure resonant frequencies will be covered is selected as a prudent tactic.

Thus as the pressure is increased on the globe, intraocular pressure will rise. Increases in IOP will increase the acoustic damping. Increased damping will be reflected in a reduction in intensity of the signal recorded at both sensors placed comfortably over the closed eyelid.

The sensors will be constructed of piezoelectric film, coated with Mylar. Half the sensor will receive the vibrations of the eye and the second half will be a driving actuator. Alternatively a driving actuator can be placed anywhere on the skin of the head.

Algorithms have been developed to compare the signals between the eyes and compute an equivalent intracranial pressure. Exact calibration remains to be performed.

Additional value using this technique to measure ICP may lie with its use in conjunction with transcranial acoustical measurements. In this manner, changes in an acoustical signal generated at the eye may be measured transcranially or transcranially produced acoustical signals could be measured at the eye with the above system. Thus as ICP changes, the acoustical signals generated across these points will be changed. Furthermore, the ability to bilaterally measure the signals using both eyes may assist in confirming measures. Alternatively, the potential may exist to allow detection of hemispheric location of large accumulations of intracranial blood after trauma such as epidural and subdural hematomas.

3. What is novel or unusual about this invention? How does it differ from present technology? What are its advantages?

non invasive acoustical comfortable monitor

4. What is the closest technology currently available, upon which this invention improves?

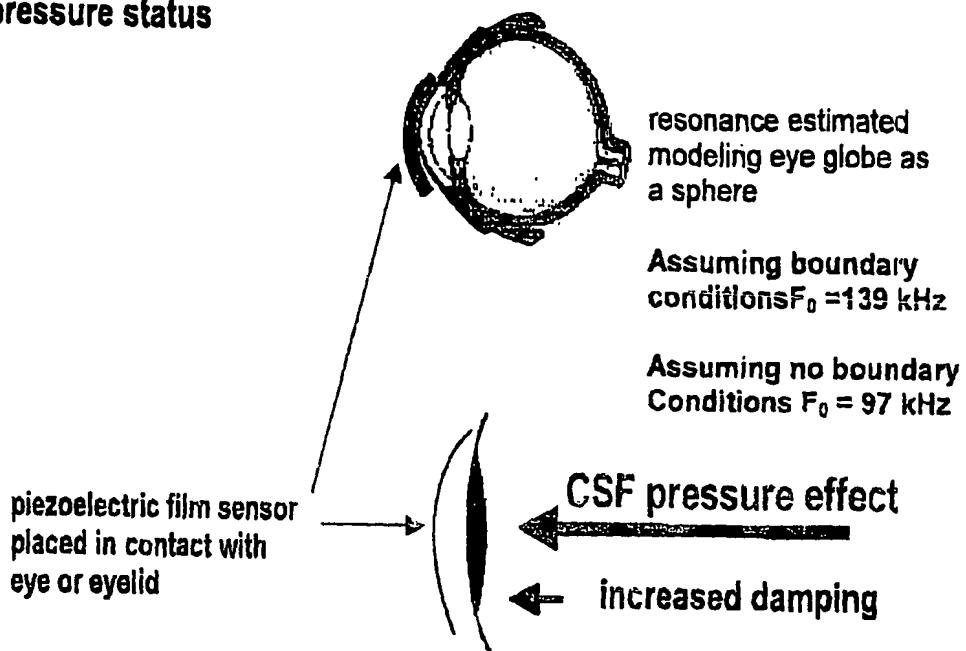
air tonometry, ophthalmodynamometry

6. What uses do you foresee for the invention, both now and in the future?

broad application in emergency medicine, critical care medicine, trauma surgery, neurology, neurosurgery and internal medicine, military medicine, aviation/space medicine

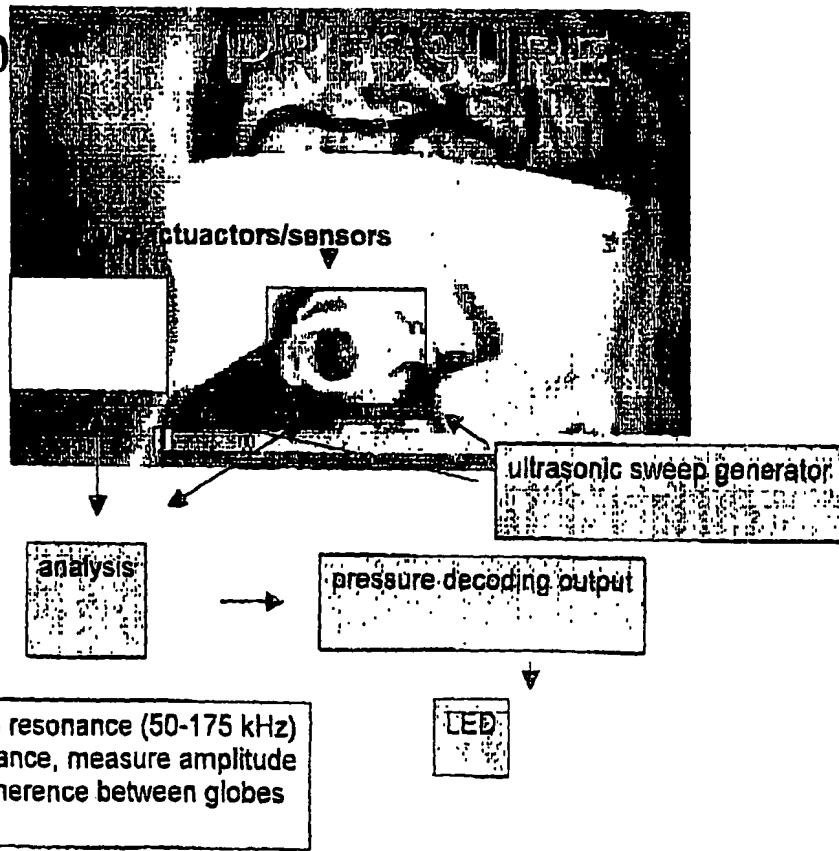
An increase in brain pressure, if goes undetected and untreated, is potentially fatal. Brain pressure can be monitored by acoustic eye patches which are comfortable, accurate and provide a rapid and sensitive reading.

eye resonance pressure effect as an indicator of cerebral fluid pressure status



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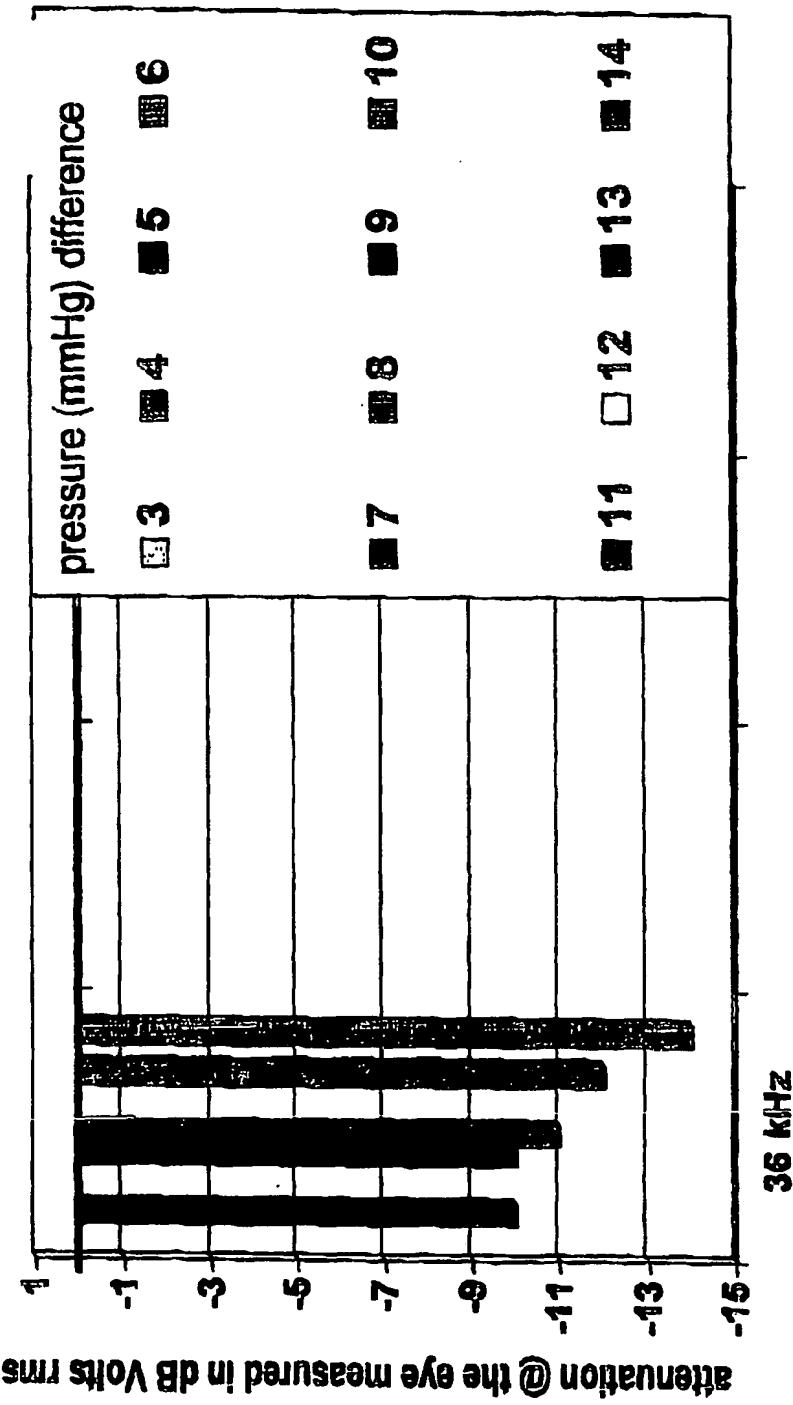
METHOD



Data from five subjects are presented in which recording from the eye, in response to head vibration, reveals the pattern of decreased acoustic transmission (damping) with increasing ICP. This relationship is graphically displayed in the first figure.

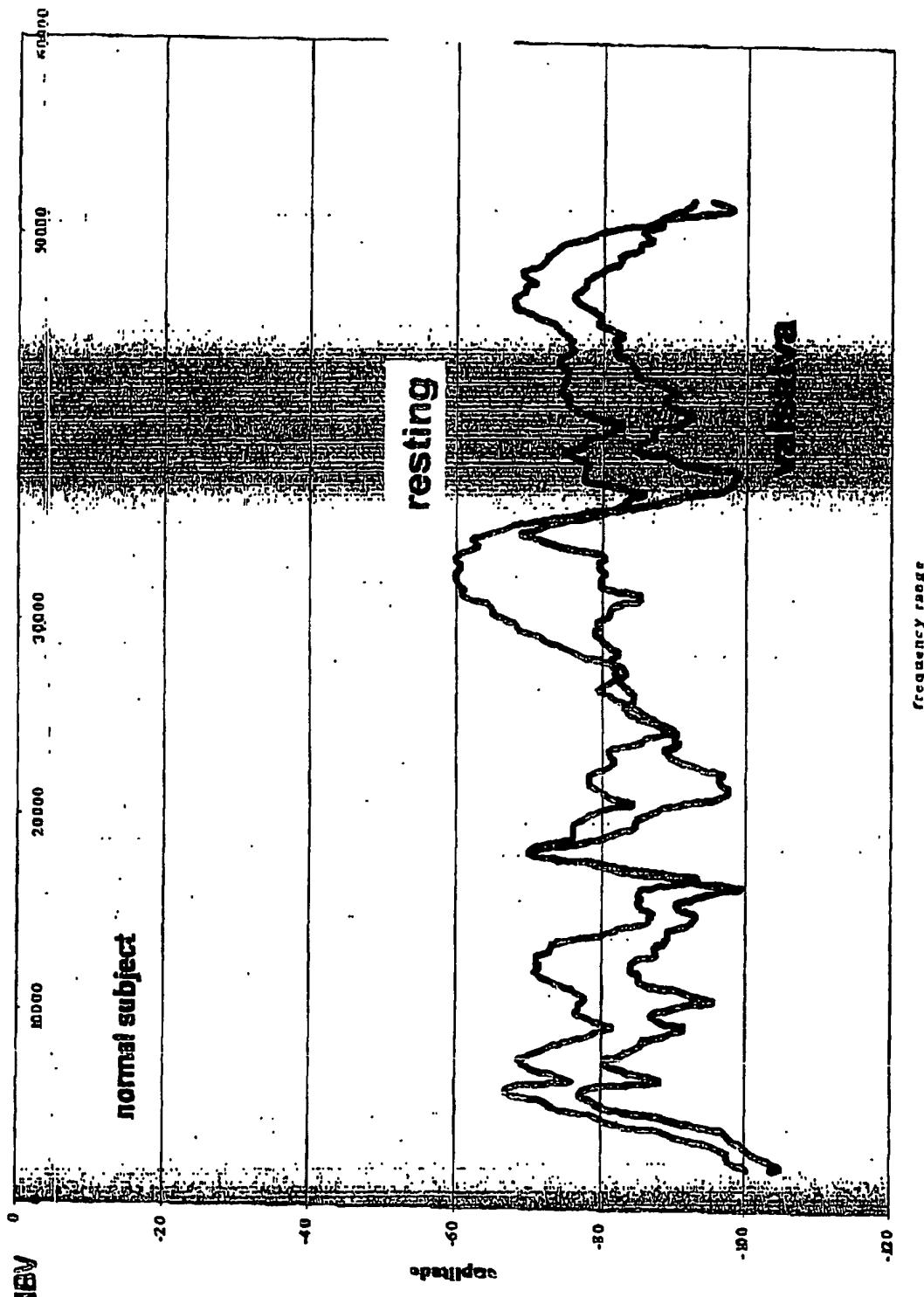
Patient Initials	Invasive Method Monitoring	ICP
HB	Ventriculostomy	7 mm Hg.
GC	Ventriculostomy	11 mm Hg.
GJ	Ventriculostomy	15 mm Hg.
RR	Ventriculostomy	20 mm Hg.
BP	Ventriculostomy	18 mm Hg.

Attenuation (dBV_{rms}) with ICP increase with eye recording



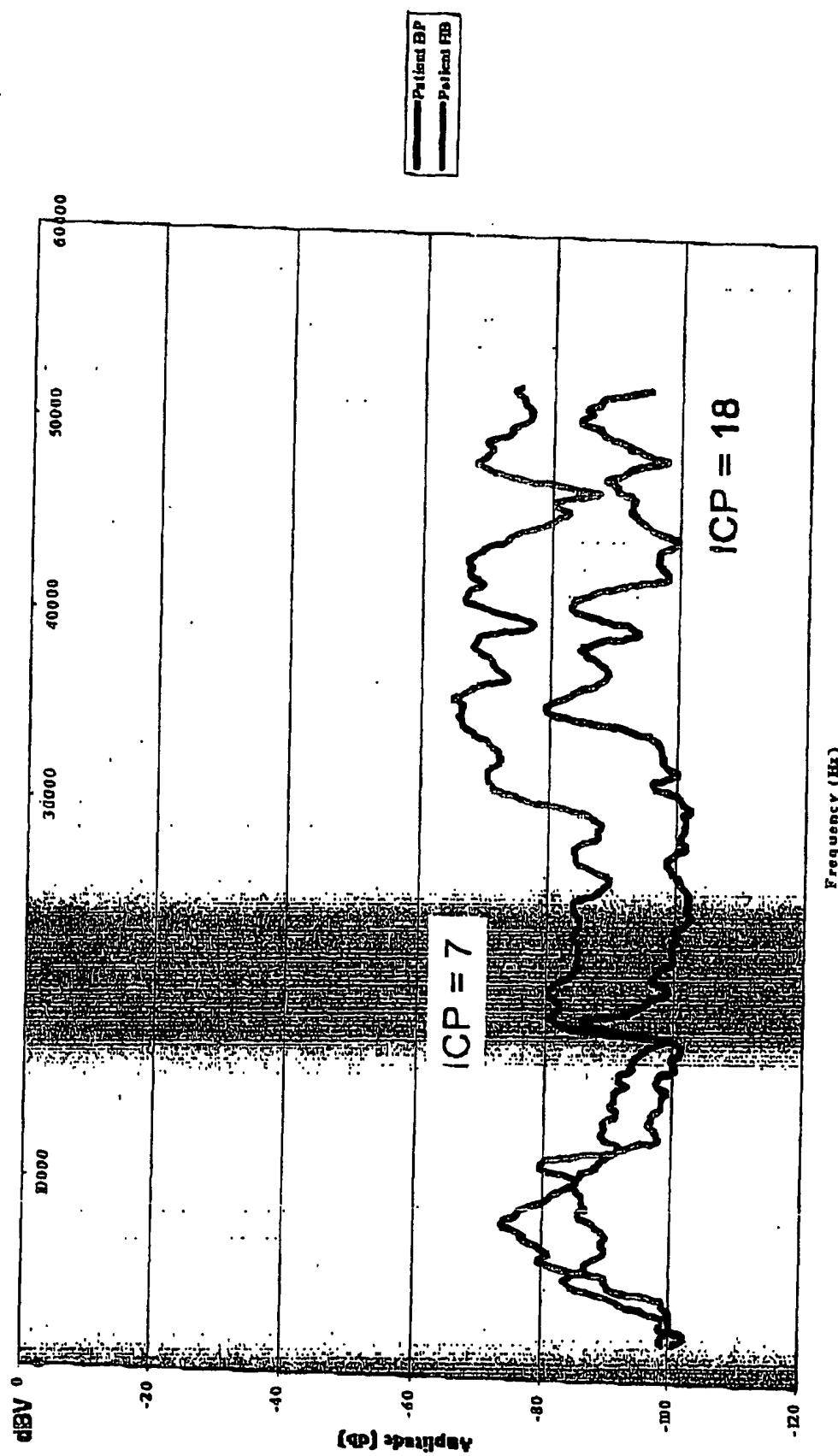
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eye voltage reading versus moment



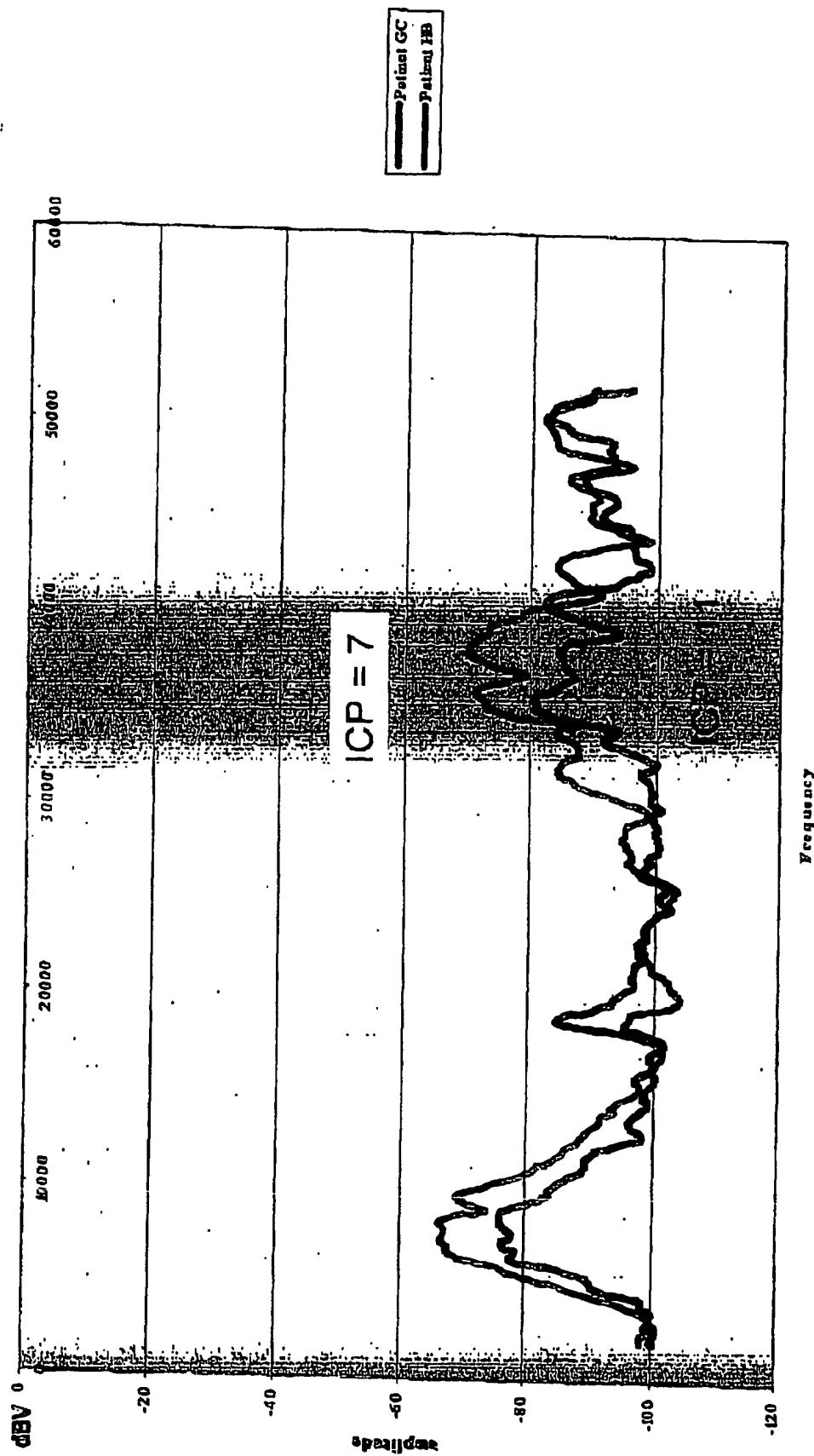
DATA ANALYSIS

Comparing Patient HB and Patient BP



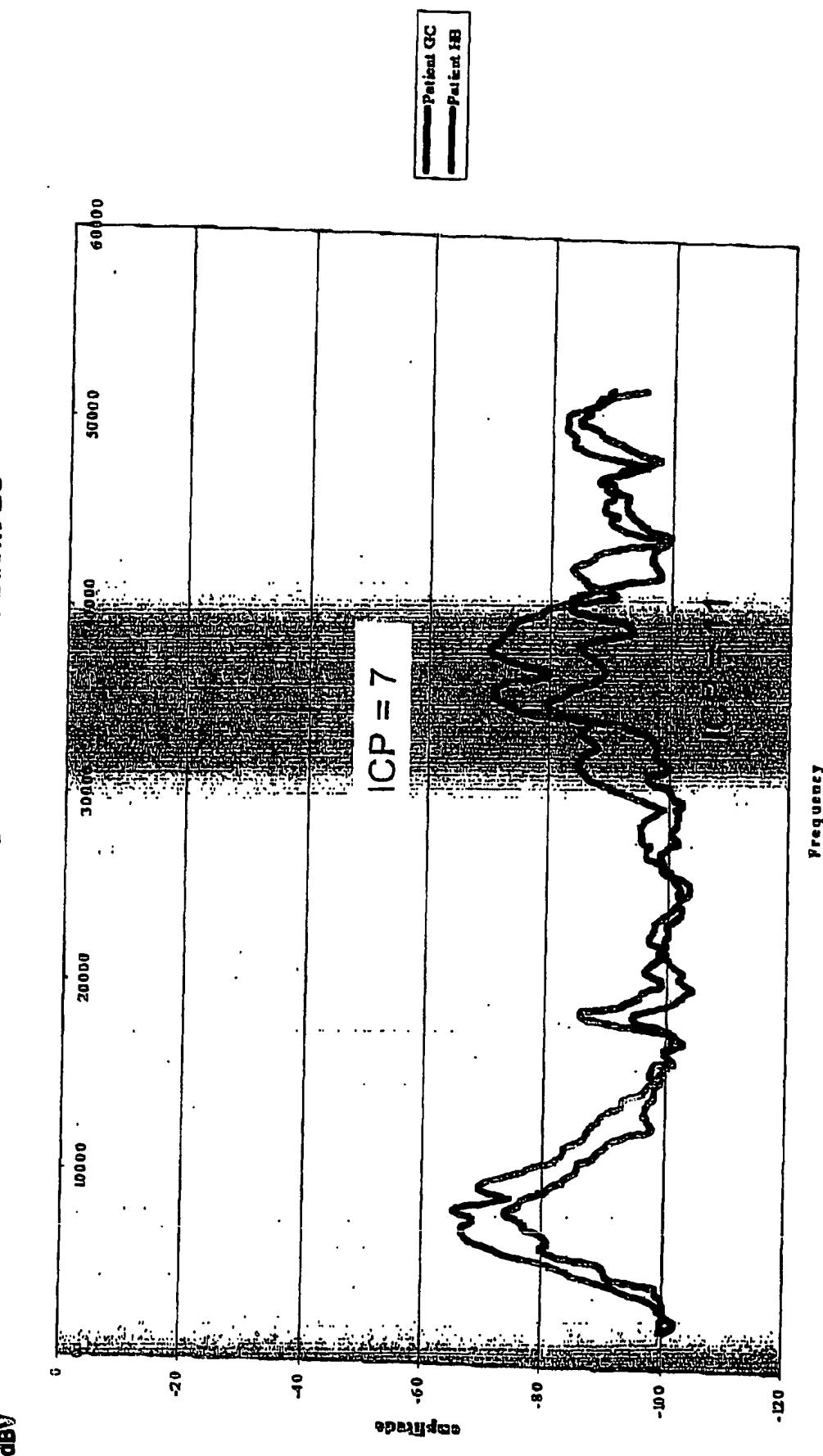
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Comparing Patient HB and GC



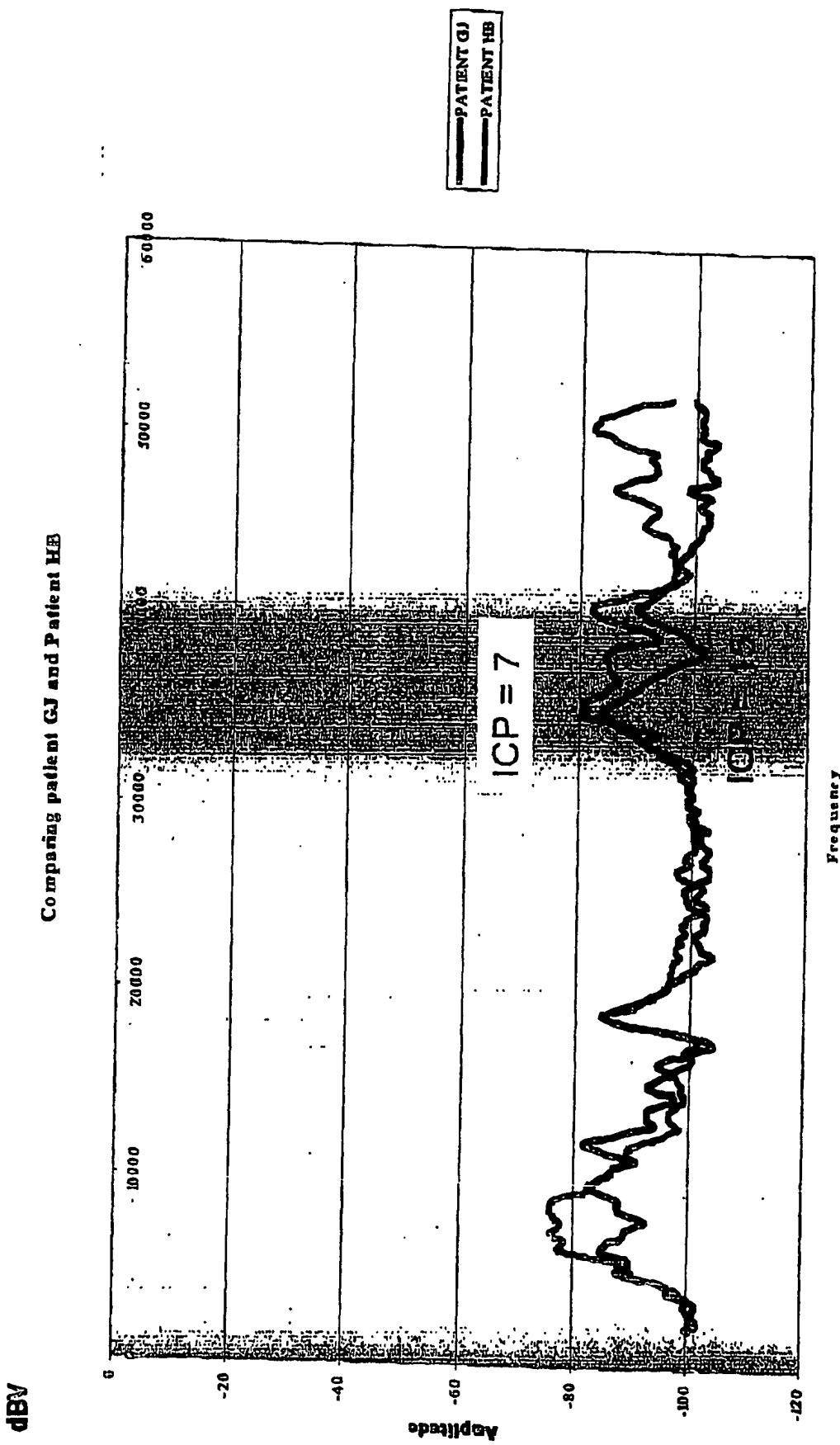
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Comparing Patient HB and Patient GC



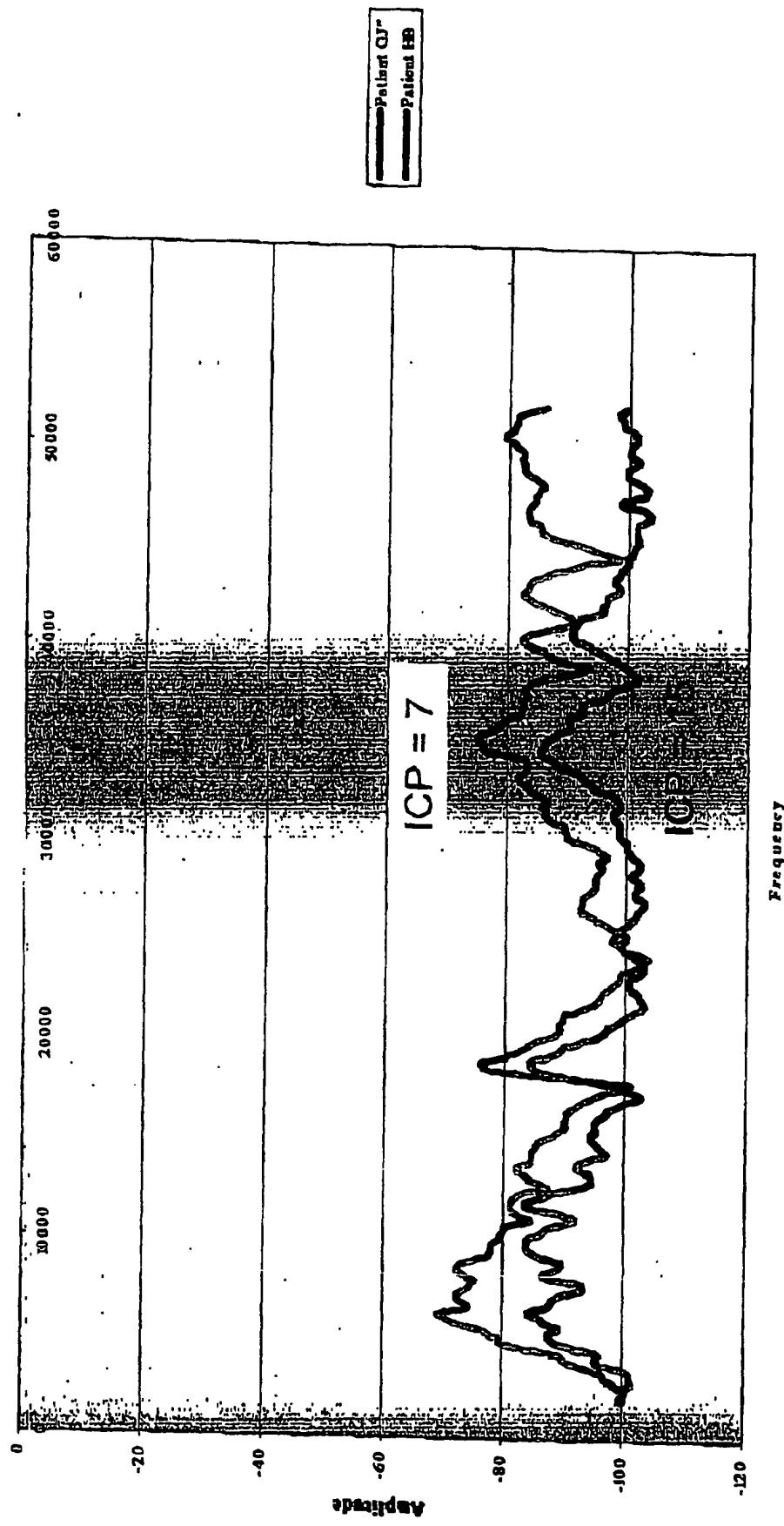
ACOUSTIC COORD

Comparing patient GJ and Patient HB



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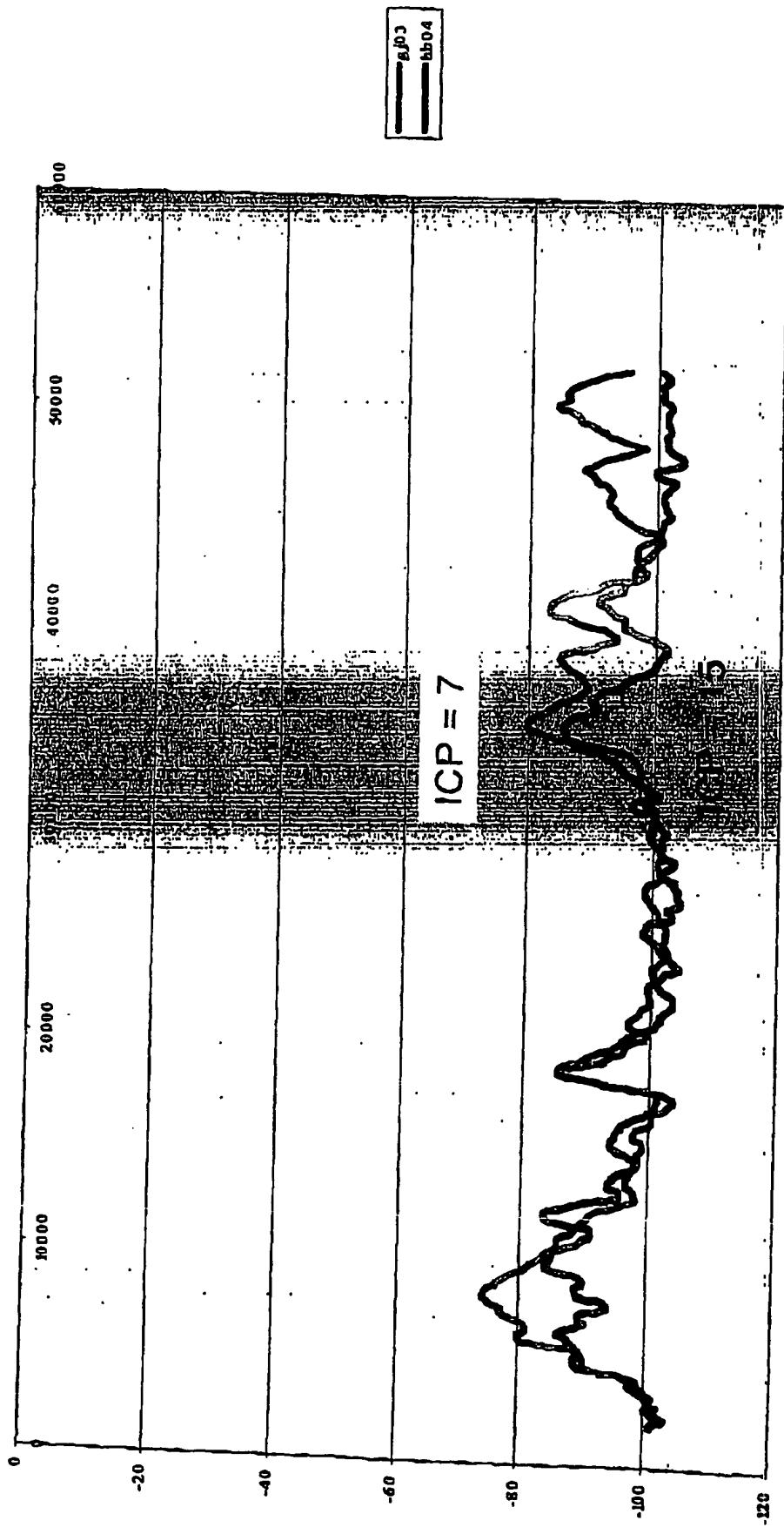
Comparing Patient GJ and Patient HB



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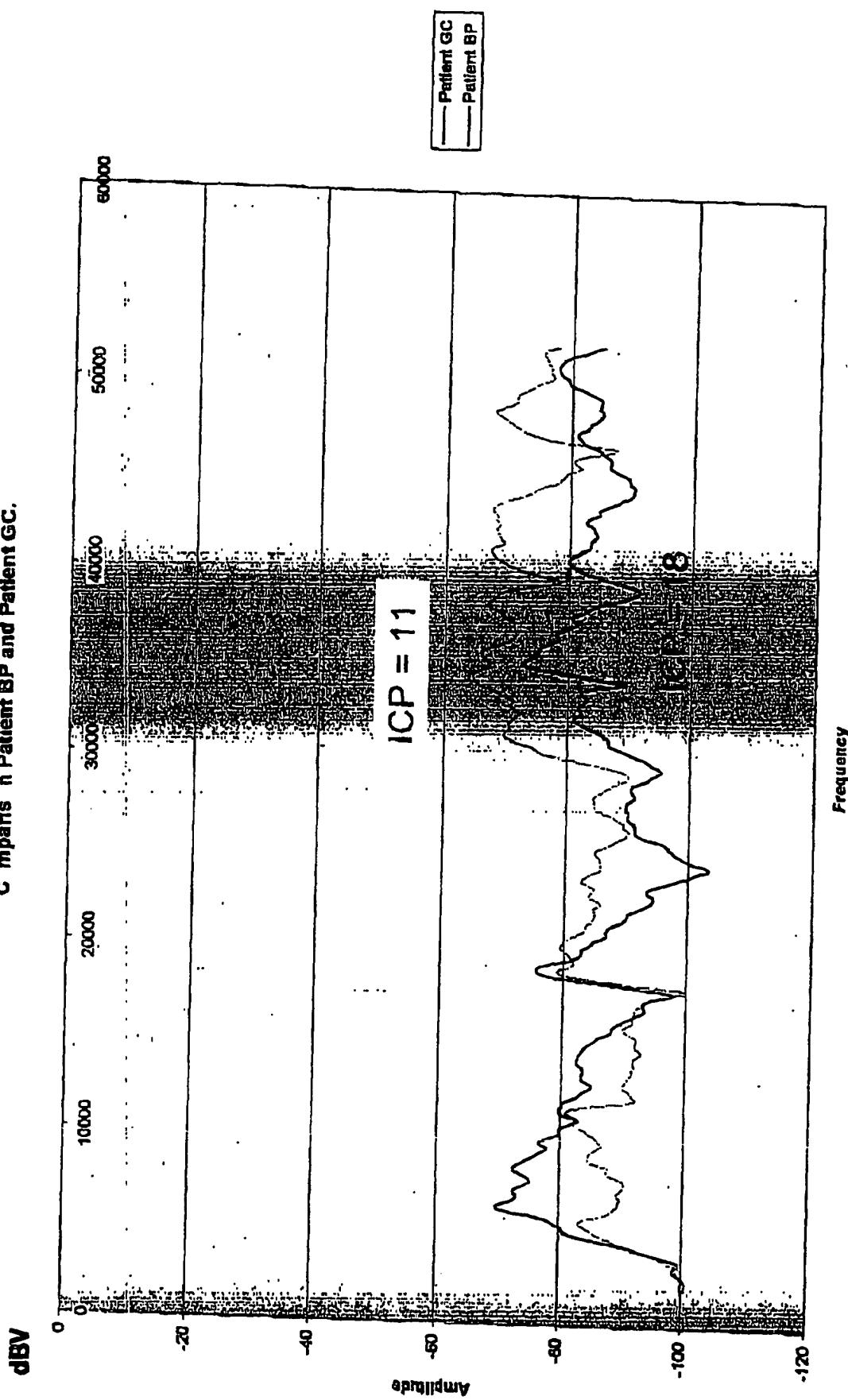
compare sheet 2

dBV



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Comparison Patient BP and Patient GC.



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Comparing Patient RR and GC

